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Heparin - coated stents cut complications by 30%

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Six months after treatment, a heparin-coated stent reduced the incidence of clinical events caused by angioplasty by 27%, according to results from the Benestent II trial presented by Dr Patrick Serruys, of Erasmus University in Rotterdam, the Netherlands.

Previous trials, including the Benestent I trial, showed that stents significantly reduce the incidence of clinical events and restenosis associated with balloon angioplasty. However, the aggressive anticoagulation regimen needed to prevent stent-thrombosis and suboptimal stent implantation resulted in excessive bleeding complications and subacute occlusion.

Intravascular ultrasound studies have shown that high-pressure balloon inflation virtually guarantees proper placement, which reduces occlusions, leaving bleeding as the most significant complication to stenting.

Johnson and Johnson Interventional System's(*) answer was to coat a stent with heparin, hoping that it would still prevent stent-thrombosis, but avoid the problems of systemic anticoagulation. This led to the initiation of the Benestent II trial, which used heparin-coated Palmaz-Schatz stents in conjunction with ticlopidine and aspirin medication - a combination that has been proved to cut bleeding complications.

The trial randomised 827 angina patients in 14 countries to receive either PTCA alone or PTCA followed by stenting.

Intervention was considered a procedural success in 97% of cases in the stent group and 86% in the PTCA group. After 15 days, as reported in August, at the European Society of Cardiology meeting in Birmingham (see Clinica No 720/21, p 22-3), there were no significant differences in the rate of death, MI, or reintervention between the two groups.

At six months, however, the overall rate of clinical events was 27% lower in the stent group; at 14.5% compared with 19.9% in the PTCA group. The need for revascularisation was reduced by over a third in the stent group. The rate of subacute occlusion was 0.2% in the stent group compared with 1.9% in the PTCA group. The new stent, said Dr. Serruys, "virtually eliminates the risk of subacute occlusion".

Overall there were 60 cases of death, MI, or repeat PTCA or bypass surgery among the stent patients versus 82 in the PTCA group. Dr Serruys said the presence of stents improved results even in the PTCA alone group - because 55 of these patients needed a stent to counter complications of the angioplasty. This compares with 12 patients in the stent group who underwent bypass surgery, did not receive a stent, or received a different stent.

The use of emergency stenting during angioplasty reduced clinical events to below 20%, representing an historic new low. For the interventionalist, said Dr. Serruys, "the escape route of bailout stenting" encourages them to be "more aggressive in dilating the lesion with the balloon".(*) Since the start of Benestent II,

Johnson & Johnson Interventional Systems, makers of the Palmaz-Schatz stent, has changed its name to Cordis.